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K003636

VARIAN
medical systems

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Premarket Notification [510K] Summary as required by 21 CFR 807.92

Date Summary was prepared:
November 13, 2000

Submitter's Name:
Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Person:
Linda S. Nash
Corporate Director, Regulatory Affairs and Quality Assurance
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Device Name:
Portalvision

Classification Name:
Medical Charged Particle Radiation Therapy, Accessory

Predicate Device: Varis Portalvision

Product Description: See the Description of the Device, Tab F

Intended Use:

Portalvision is an online electronic portal imaging system, which allows verification of the treatment filed, shielding and beam-shaping device, including but not limited to blocks and Multileaf Collimator, in relation to anatomical landmarks in the radiation therapy treatment. In addition, the device provides tools for the verification of the dose delivered to the patient.

Technological Characteristics:
See the "Specification Comparison Chart", Tab G.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Linda S. Nash
Corporate Director, Regulatory Affairs
and Quality Assurance
Varian Medical Systems
3100 Hansen Way M/S H-055
PALO ALTO CA 94304-1129

Re: K003636
Portalvision (Electronic Portal Imaging Device)
Dated: November 14, 2000
Received: November 24, 2000
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Nash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

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Indications for Use

510(k) Number (if known): K003636

Device Name: Portalvision

Indications for Use:

The Portalvision device is used for verification of the treatment field and shielding blocks in relation to anatomical landmarks in radiotherapy treatment. Portalvision will also allow for verification of the exit dose in radiotherapy treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003636